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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/752,871	01/06/2004	Stephen Donovan	17359CON2CIP1C1P1 (BOT)	4854

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EXAMINER	
FOLEY, SHANON A	
ART UNIT	PAPER NUMBER
1619	
MAIL DATE	DELIVERY MODE
03/04/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/752,871	DONOVAN, STEPHEN	
	Examiner	Art Unit	
	SHANON A. FOLEY	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,5,8 and 14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4, 5, 8 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Group and/or Art Unit of your application has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1648, Examiner Foley.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4, 5, 8 remain rejected and new claim 14 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 7-15, 18 of U.S. Patent No. 6,383,509. Although the conflicting claims are not identical, they are not patentably distinct from each other because nothing precluded applicant from claiming the implant for the eye, or precluded from incorporating the various conventional botulinum toxin type A complexes produced (as discussed in column 5, lines 14-29 of '509), as is now claimed.

It is noted that Applicant has not responded to this previous rejection of record through arguments or filing a terminal disclaimer. The rejection is maintained for reasons of record.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4, 5, 8 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singh et al., cited in the previous Office action and Aoki et al. (US 6,113,915).

The claims are drawn to an implant for treating a medical condition of the eye, which comprises a carrier and a botulinum neurotoxin, preferably type A, complex having a molecular weight of about 900, 700, 500, or 300 kD that is associated with the carrier, wherein a therapeutic amount of the botulinum neurotoxin can be released from the carrier upon implantation into a patient to treat a condition of the eye. The carrier is biodegradable and the botulinum neurotoxin serotypes are selected from A-G. The claims also encompass a method of treating a condition of the eye by administering the biodegradable implant.

Singh discloses a composition comprising Hn-33, which is a biologically active, protease resistant hemagglutinin isolated from *Clostridium botulinum* neurotoxin, in combination with at least one neurotoxin, e.g., type A or E botulinum neurotoxin. See especially column 1, line 53 to column 2, line 10. Therapeutic compositions are disclosed in column 11. Note that various disorders including strabismus are disclosed. Therapeutic carriers are disclosed in column 11, lines 21-47. Regarding claim 4, see column 11, line 41.

Singh et al. do not teach that the botulinum neurotoxin is selected from serotypes A-G or that they have a molecular weight of specific kD.

However, Aoki et al. teach that botulinum toxins are released from the *Clostridium* bacterium as complexes. Botulinum type A is produced as 900, 500 and 300 kD forms; types B and C1 are produced as 500 kD forms; type D is produced at 300 and 500 kD forms and types E and F are produced as 300 kD complexes, see column 5, lines 1-25.

One of ordinary skill in the art at the time the invention was made would have been motivated to use the botulinum toxin complexes that are released from the various Clostridium botulinum types A-F in the composition and method of Singh et al. because Aoki et al. teach that the intact botulinum toxin complexes provide stability and have a slower rate of diffusion within an intramuscular site, see column 5, lines 16-25. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation for combining the botulinum neurotoxins of Aoki et al. with the composition and method of Singh et al. because Singh et al. teach the inclusion of any botulinum neurotoxin in the complex, see column 2, lines 1-10, line 35 to column 3, line 4 and claims 1-5.

Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

In response to the grounds of rejection applied with Singh et al., applicant argues that Singh et al. use a 33 kDa hemagglutinin complexed to an isolated botulinum neurotoxin of about 150 kDa. Applicant refers to column 14, lines 40-45 and column 19 Of Singh et al. Applicant

argues that Singh et al. do not teach or suggest incorporating botulinum neurotoxin of the types and molecular weights recited in the claims.

A review of the teachings of Singh et al. and applicant's arguments have been fully considered, but are found unpersuasive. Columns 14 and 19 of Singh et al. are working examples of the instant botulinum toxin-carrier complexes. These examples are not representative of the scope of embodiments encompassed within the disclosure and claims 1-5 of Singh et al. Since the complex of Singh et al. encompasses any botulinum toxin complex, the complexes naturally released from the various *Clostridium botulinum* types A-F, as taught by Aoki et al., would have been obvious design choices to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHANON A. FOLEY whose telephone number is (571)272-0898. The examiner can normally be reached on M-F 5:30 AM-3 PM, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shanon A. Foley/
Primary Examiner
Art Unit 1619